REMARKS

Claims 1 – 6 and 8 - 20 were pending in this application.

Claims 1 – 6 and 8 - 20 were rejected.

I. 35 USC 103(a) Rejections

The Examiner has rejected Claims 1 –9 and 12-18 under 35 USC 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0107117 to Denny in view of U.S. Patent Application Publication No. 2003/0074225 to Borsand.

The rejected claims contain two independent claims, which are Claim 1 and Claim 12. Both Claim 1 and Claim 12 are believed to be distinguishable over both the Denny and Borsand references as is explained below.

Claim 1

Claim 1 sets forth a method of tracking the execution of a medical prescription by medical service professionals. To achieve this method, a database is provided. In a physician's office, a physician examines a patient and writes a prescription for that patient. The prescription is initially unfilled. Unfilled prescription data that corresponds to the prescription is entered into the database. The unfilled prescription data contains information regarding a recommended pharmaceutical type and a recommended quantity recommended by the physician in the prescription.

The patient travels to a pharmacy to have the prescription filled. At the pharmacy, the unfilled prescription data is retrieved from the database. Using the retrieved data, the prescription is filled. The filled prescription contains a presented pharmaceutical type in a presented quantity. The actual pharmaceutical presented and its quantity may or may not correspond with the

unfilled prescription data for a variety of reasons, such as mistake , fraud or simple pharmacist discretion..

Data corresponding to how the prescription is actually filled is entered into the database by the pharmacist. The filled prescription data includes information regarding the actual presented pharmaceutical type and its quantity.

The filled prescription data is compared to the unfilled prescription data. If the two data sets do not match , then a warning is generated. The warning indicates that the prescription has been varied in some manner. If the data sets do not match, a warning is generated and is sent to the physician who first wrote the prescription. The physician, upon receipt of the warning, can contact the patient or pharmacist to correct and mistake.

The Denny reference shows a database system for ensuring that a prescription is properly filled. Like the present invention, a physician enters a prescription into a database. Furthermore, like the present invention, a pharmacist recalls the prescription from the database. In this manner, the need for a handwritten prescription is eliminated.

However, the present invention method significantly differs from the Denny reference in how the data from the database is used. As is claimed by Claim 1 of the present application, the pharmacist is required to enter filled prescription data back into the database. The filled prescription data contains information regarding the actual pharmaceutical and the actual amount of the pharmaceutical that was handed the patient. The filled prescription data is actively compared to the data of the initial prescription. If the initial prescription does not match the actual pharmaceutical and amounts given to the patent, then a warning is generated. The warning is communicated back to the physician who wrote the initial prescription.

The Denny reference makes absolutely no disclosure concerning the method step of having a pharmacist enter filled prescription data back into the database. In the Denny reference, it is clearly stated that the initial prescription is read from a database. The initial proscription comes with a "confirmation code". The confirmation code is entered to inform the database that the prescription information was received. (See Denny, paragraph 0038).

The Denny reference makes no disclosure of entering filled prescription data back into

the database. Consequently, the Denny reference also makes no disclosure of comparing the filled prescription data with the initial unfilled prescription date. The Denney reference, therefore, fails to make any disclosure concerning producing a warning that is sent back to the physician if the two data sets do not match.

In the Office Action dated 09/06/2006 on page 3, bottom of 1st paragraph, the Examiner states the claimed method step of "entering filled prescription data into said database" is shown by "(Denny; paragraphs {0035] [0041]". This statement is not true. Paragraphs [0035] and [0041] of the Denny patent are reproduced below

[0035] Referring now to **FIG. 3**, one embodiment of the pharmacy system **16** is shown. The pharmacy system **16** includes an input device **70**, an output device **72**, a central processing unit (CPU) **74**, a printer **76**, and the communication channel **20**. The users of the pharmacy system **16**, such as pharmacists, pharmacists' assistants, and administrative personnel associated with the pharmacy, can input information representative or indicative of a prescription to be filled into the pharmacy system **16** via the input device **70** to retrieve the retrieval information discussed above, and, in some instances when authorization is obtained by a physician, to input the prescription information. The input device **70** may be any device capable of inputting information into the pharmacy system **16**, such as a keyboard, mouse, scanner, voice-recognition, or other similar devices. The information input into the input device **70** is transmitted along line **78** to the central processing unit **74** for communication to the host system **12** via the communication channel **20**.

[0041] Once the pharmacy system **16** is connected to the host system **12**, the host system **12** processes prescription information received from the pharmacy system **16** during a step **128** and a line **130**. For example, after receiving a prescription, the patient can travel to one of the patient-selected pharmacies and present the printout of the prescription information to a pharmacist. The pharmacist enters the unique code identifying the prescription or other information identifying the patient into the pharmacy system **16** to affect retrieval of the prescription from the host system **12**. During the step **128**, the patient prescription information is received by the pharmacy system **16** from the host system **12**, the prescription is filled by the pharmacist associated with the pharmacy system **16**, and a confirmation code indicative of a prescription being filled is input into the host system **12** by the pharmacy system **16**. Thereafter, the pharmacy system **16** disconnects from the host system **12**, such as by termi-

As can be seen by the highlighted section of paragraph [0035] the Denny patent only discloses that a pharmacy enters data about the prescription ***"to be filled"***. The prescription to be filled is simply the prescription carried into the pharmacy by the patient. The Denny patent makes no disclosure of entering any information concerning how the prescription was actually filled. If the prescription was altered by changing drug brand, pill size, pill type, pill number , such information is never entered into the system of the Denny patent. the prescription that was actually filled

As can be seen by the highlighted section of paragraph [0041] the Denny patent only discloses that a pharmacy enters data about the confirmation code that comes with the

prescription. The initial proscription comes with a "confirmation code". The confirmation code is entered to inform the database that the prescription information was received. (See earlier in Denny, paragraph 0038). Again, the Denny patent makes no disclosure of entering any information concerning how the prescription was actually filled.

In the Office Action dated 09/06/2006 on page 3, bottom of 1st paragraph, the Examiner states the claimed method step of "comparing said filled prescription data with said unfilled prescription data" is shown by "(Denny; paragraph [0053])". The Examiner's statement is also not true. Paragraphs [0053] and a portion of paragraph [0052] of the Denny patent are reproduced below

is received by the host system **12** at a step **226**, as indicated by a line **224**. It should be noted that when the database wherein the prescription information is maintained includes a confirmation code field, i.e., the confirmation code, intended to identify whether not a prescription has been filled, the confirmation code is communicated with the prescription information.

[0053] Thereafter, the host system **12** determines whether or not the data received is valid based upon querying the prescription database by a step **228**, as indicated by a line **230**. Where the information received from the pharmacy system **16** corresponds to prescription information maintained in the host system **12** database, the process branches to a step **234**, indicated by a line **232**, and transmits a signal to the health care provider **14** or pharmacy system **16** indicating that the prescription information entered is valid. However, where the information received from the pharmacy system **16** does not correspond to prescription information maintained in the host system **12** database, the process branches to a step **238**, as indicated by a line **236**, and transmits a signal to the health care provider system **14** or pharmacy system **16** indicating that the prescription information entered is invalid.

It is very clear from paragraph [0052] that the "prescription information" referred to in paragraph [0053] is the confirmation code. The Denny patent therefore uses the conformation code to confirm that a particular prescription for a particular patient has been processed by a pharmacy. Again, it is pointed out to the Examiner that the confirmation code contains no information regarding how the pharmacist actually filled a prescription. The confirmation code merely is a tracking code that shows a prescription has been received by a pharmacy.

The Denney reference, therefore, clearly fails to disclose the last three method steps of Claim 1, which are

> ***"entering filled prescription data into said database, wherein said filled prescription data includes information for said presented pharmaceutical type and said presented quantity;***
>
> ***comparing said filled prescription data with said unfilled prescription data; and***
>
> ***generating a warning if said filled prescription data does not match said unfilled prescription data, wherein said warning is forwarded to said physician who initial wrote said prescription".***

In the last Office action, on page 4, 1st paragraph, the Examiner admits that the "Denny fails to specifically indicate that the pharmacist enters filled prescription data". To address this deficiency in the Denny patent, the Examiner cites the Borsand patent. **The Examiner** states that Borsand teaches "a method wherein filled prescription data includes information for said presented pharmaceutical type and said presented quantity. In support of this statement, the Examiner cites Borsand, paragraphs 0005, 0040,0056,0064,0086 and 0118.

None of the paragraphs cited by the examiner show what the Examiner states. Paragraphs 005 and 0040 of the Borsand patent are presented below.

[0005] The failure of existing systems to manage information in an efficient manner results in unnecessary health risks. A prescribing physician may not realize the extent or nature of a patient's pharmaceutical history before a drug is prescribed. It would be helpful if timely feedback were provided relating to potential pharmaceutical conflicts or with respect to allergic reactions to pharmaceutical products. It would also be helpful if a provider could view treatment protocols, up-to-date formulary lists, benefit designs, and convey accurate pharmaceutical prescriptions to pharmacies without the necessity of a pharmacist struggling to read the handwritten prescription. It would also be advantageous if a physician could monitor a patient's pharmaceutical compliance and utilization, canceling such prescriptions when helpful to avoid the misuse of such prescriptions. For example, it would be desirable if a pharmacist could be prevented from filling a prescription at half strength but twice the volume and cost. It would also be desirable if a pharmacists could be prevented from filling redundant prescriptions from two or more providers.

[0040] In contrast to FIG. 1, which illustrates a system 20 in which the payor 60, PBM 50, pharmacy 40, and provider access and manipulate the same information on the computer 26, the prior art does not provide such an integrated system. FIG. 2 discloses a high-level view of a typical prior art system. In a typical prior art system, a provider 30 deals solely with the patient 22, and generally has no pharmaceutical-related communication with the pharmacist 40, PBM 50, or payor 60 before issuing a prescription 28. At most, the provider 30 may receive a quick phone call from a pharmacy 40 after the provider 30 has issued a prescription 28 to confirm a prescription 28 or to inform that provider 30 that a payor 60 or PBM 50 has denied reimbursement 27 of a particular claim 36. A pharmacy 40 has no direct contact with a payor 60 in the prior art, and instead relies on communicating with the PBM 50 as a middle-man. In the prior art, the PBM 50 is the only entity that can directly access a payor 60 and its reimbursement rules 34. More specifically, any attempt by a provider 30 to certify a prescription 28 must go through both the pharmacy 40 and the PBM 50 to ultimately reach the payor 60. The payor's 60 feedback is similarly indirect, going first through the PBM 50 and pharmacy 40 before reaching the provider 30.

As can be seen neither paragraph in any manner mentions the database entry of data corresponding to how a prescription was actually filled. The Examiner is invited to explain the relevance of these cited paragraphs because they have no relevance ascertainable by the applicant.

In regard to paragraphs 0056 and 0064, these paragraphs are reproduced below.

[0056] The capabilities of the prescription subsystem are enhanced by the ability of the prescription subsystem to communicate with the reimbursement subsystem and the pharmaceutical subsystem. The prescription subsystem allows health care providers 30 to interact with payors 60, PBMs 50, and pharmacists 40 in an efficient and proactive manner saving providers 30 both time and money 44. By allowing providers 30 to generate pre-certified 38 prescriptions 28, the total number of transactions, activities, reworks, and follow-ups is reduced for all of the parties involved. Allowing both providers 30 and pharmacies 40 to manage their interactions using the system 20 may substantially reduce the time pharmacists 40 and providers 30 spend trying to call each other on the phone to clarify or remedy prescription discrepancies. The provider 30 can monitor whether or not a patient 30 actually fills the prescription 28 because fulfillment of the prescription results in the appropriate data being entered by the pharmacist 30. Medication history is available to the provider 30 even if the medication was prescribed by a different provider 30 because the prescription 28 by the other provider 30 would be on the system, as would the fulfillment of such a prescription 28 by a pharmacist 40. Use of the system 20 provides the provider 30 and other entities with a centralized location for patient 22 information maximizing the probability that pharmaceutical interactions and allergic reactions would be detected before a prescription 28 is issued for a particular pharmaceutical 32. Changes in a payor's 60 treatment protocols, reimbursement rules 34, formulary 24, or other superceding events can be reacted to by a provider 30 in a substantially simultaneous manner by modifying or even canceling a prescription 32. Patient 22 refill behavior can be monitored

[0064] The prescription detail page at 30.36 allows the provider to enter a diagnosis at 30.52 of the patient's 22 medical condition. The prescription subsystem supports multiple diagnoses for the same patient 22 and prescription 28. The strength of a particular pharmaceutical 32 is part of the pharmaceutical 32. The quantity of the pharmaceutical 32 is a separate characteristic which can then be entered at 30.54. SIG, which is pharmaceutical term of art relating to the directions for a particular pharmaceutical 32. SIG can be selected at 30.56. The number of days that a patient 22 is to take the prescribed pharmaceutical is set at 30.58, and the number of permitted refills is set at 30.60. The provider 30 may add whatever additional comments or notes are desired at 30.62. The prescription subsystem then computes estimated costs at 30.64 based on the unit price information contained in the system 20. If the provider 30 wants to cancel to prescription 28, the provider can choose to do so at 30.66, and return to the patient record page at 30.07. If the prescription 28 is issued at 30.68, the output is sent to the confirm prescription page at 30.70.

Paragraphs 0056 and 0064 discuss how data in the database of the Borsand patent can be used. However, neither paragraph in any way discloses or mentions that data regarding how a prescription is actually filled is entered to a database.

In regard to paragraphs 0086 and 0118, these paragraphs are reproduced below.

[0086] The process of filling or re-filling a pharmaceutical **32** prescription **28** triggers the activation of the java script at **40.06**. If the prescription **28** was not sent electronically through the system **28**, then the prescription **28** information needs to be inputted into the system at **40.08**. The inputting of prescription information can be done in many different ways. A bar code label on the paper prescription **28** could be used to generate the appropriate information in the system **20**. The pharmacist **40** could type the data into the system **20**, or use a voice recognition technology to enter the information into the system **20**. In a preferred embodiment of the invention, the prescription subsystem sends the prescription **28** in an electronic format to the pharmaceutical subsystem.

[0118] The pharmacist **40** can then fill the prescription **28** at **124**. In a preferred embodiment of the invention, an electronic representation of the filling of the prescription **28** is entered on the system **28** in a substantially simultaneous manner as the pharmacist **40** fills the prescription **28**. In a preferred embodiment, payment **26** is sent to the pharmacy **40** in a substantially simultaneous manner at **128** as the patient receives the pharmaceutical at **126**.

In both paragraph 0086 and paragraph 0118, it clear that the Borsand patent discloses entering the data corresponding to a prescription into a database, that is transferring the information from the prescription into the database. The Borsand patent says absolutely nothing about having a pharmacist enter information into a database that discloses **how the pharmacist has user his/her discretion in actually filing the prescription**. Consequently, the Borsand reference makes no disclosure of comparing unfilled prescription data with filled prescription data. Accordingly, the Borsand reference does not address the deficiencies of the Denny reference as applied to the wording of Claim 1.

In combination, it is clear that neither the Denny reference nor the Borsand reference disclose or suggest the method of Claim 1. Consequently, the combination fails to support a 35 USC 103 rejection. It is therefore requested that the 35 USC 103 rejection as applied to Claim 1 and its dependent claims be withdrawn.

Claim 12

Claim 1 sets forth a method of reducing fraud and mistake in the filling of medical prescriptions. Like Claim 1, Claim 12 includes the step of entering filled prescription data into a database, wherein the filled prescription data identifies a pharmaceutical and volume actually provided by a pharmacist. The filled prescription data is compared to the initial unfilled prescription data. If there is no match between data sets, a warning is produced.

As has been previously explained, the Denny and Borsand patents do not disclose or suggest the entry of filled prescription data into a database by a pharmacist. The combination also does not disclose the comparison of the filled prescription data with the unfilled prescription data. Consequently, the combination fails to support a 35 USC 103 rejection. It is therefore requested that the 35 USC 103 rejection as applied to Claim 1 and its dependent claims be withdrawn.

The Examiner has rejected Claims 10-11 and 19-20 under 35 USC 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0107117 to Denny in view of U.S. Patent Application Publication No. 2003/0074225 to Borsand and in further view of U.S. Patent Publication 2001/0047281.

The differences between the independent claims and the combined Denny and Borsand patents have been previously explained. The Examiner cites the Keresman patent to show that biometric identification is used to identify health care professionals. However, the Keresman patent does not disclose or suggest any system where a pharmacist enters information regarding how the pharmacist actually filled a prescription in addition to the prescription information itself. Accordingly, the Keresman patent does not disclose the deficiencies of the Denny patent or the Borsand patent as applied to the independent claims. Claims 10-11 and 19-20 are therefore believed to be patentable since they depend from, and further define, allowable base claims.

III. SUMMARY

Having fully distinguished the pending claims over the cited art, this application is believed to stand in condition for allowance. However, if the Examiner is of the opinion that such action cannot be taken, the Examiner is requested to call the applicant's attorney at (215) 321-6772 in order that any outstanding issues may be resolved without the necessity of issuing a further Office Action.

Respectfully Submitted,

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